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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/699,923 | 10/30/2000 | David H. Lynch | 2836-E | 8828 |

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| EXAMINER | |
|---|---|
| GAMBEL, PHILLIP | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/699,923 | LYNCH ET AL. | |
| | Examiner | Art Unit | |
| | Phillip Gambel | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *4/26/04; 7/26/06; 9/27/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15,16,23-25,29,36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15,16 and 23-25* is/are allowed.

6)☒ Claim(s) *29, 36, 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's amendment, filed 4/26/04, has been entered.
Claims 15, 16, 29 and 31 have been amended.

Applicant's amendment, filed 7/26/04, has been entered.
Claim 30 has been canceled. Claims 1-11 and 14 have been canceled previously.
Claims 16 and 31 have been amended
Claims 37-38 have been added.

Applicant's amendment, filed 9/27/04, has been entered.
Claims 15, 16, 29 and 38 have been amended.
Claims 17-22, 26-28, 30-35 and 37 have been canceled.

Claims 15, 16, 23-25, 29, 36 and 38 are pending.

2. This Office Action will be in response to applicant's amendments and arguments, filed 4/26/04, 7/26/04 and 9/27/04.

3. Upon reconsideration of applicant's amended claims, the previous rejection under 35 U.S.C. § 112, second paragraph, has been obviated as it reads on the current claims.

Upon reconsideration of applicant's amended claims to specify that the growth factor or cytokine "consists of flt3-ligand" or "consists of flt3-ligand and GM-CSF" in the claimed step (a) of the claimed in vitro methods, claims 15-16, 23-25 appear to be free of the prior art.

Claim 38 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 102(e) with respect to its dependency on claim 29.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 29 and 36 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lyman et al. (U.S. Patent No. 5,843,423) (see entire document) alone in view of the well known expression of CD34 on hemopoietic stem or progenitor cells at the time the invention was made, as evidenced by page 8, paragraph 2 of the instant specification .

Lyman et al. teach contacting hemopoietic stem and progenitor cells with flt-ligand alone or in conjunction with one or more cytokines, including GM-CSF to expand hemopoietic stem or progenitor cells ex vivo with flt3-L, including human flt3-L (see entire document, including column 5, paragraph 2, column 8, paragraph 4 and Example 4 on columns 23-24) to provide a cellular preparation comprising increased numbers of hemopoietic stem or progenitor cells (see column 6, paragraph 1 and Example 14).

Preamble language in terms of "an in vitro method of preparing a dendritic cell population" is an expression of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims;

Given that the starting cells population in combination with flt3-L and GM-CSF in the prior art meets the starting cell population and cytokines / growth factors recited in instant claim 29 (a); the claimed functional limitations would be inherent properties of the referenced methods to contact hemopoietic stem or progenitor cells with flt3-L and GM-CSF.

It has been well known by the ordinary artisan for over a decade that hemopoietic stem and progenitor cells express CD34, as further evidenced by page 8, paragraph 2 of the instant specification. For example, stem or progenitor cells having the CD34 maker constitute only about 1% to 3% of the mononuclear cells in the bone marrow.

7. Claims 29, 36 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable Lyman et al. (U.S. Patent No. 5,843,423) in view of Tsumamoto et al. (U.S. Patent No. 5,914,108).

Lyman et al. teach contacting hemopoietic stem and progenitor cells with flt-ligand alone or in conjunction with one or more cytokines, including GM-CSF to expand hemopoietic stem or progenitor cells ex vivo with flt3-L, including human flt3-L (see entire document, including column 5, paragraph 2, column 8, paragraph 4 and Example 4 on columns 23-24) to provide a cellular preparation comprising increased numbers of hemopoietic stem or progenitor cells (see column 6, paragraph 1 and Example 14).

Preamble language in terms of "an in vitro method of preparing a dendritic cell population" is an expression of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims;

Lyman et al. differs from the claimed methods by not disclosing the well known expression of CD34 on hemopoietic stem cells. Given that the starting cells population in combination with flt3-L and GM-CSF in the prior art meets the starting cell population and cytokines / growth factors recited in the instant claim; the claimed functional limitations would be intrinsic properties of the referenced methods to contact hemopoietic stem or progenitor cells with flt3-L and GM-CSF.

It has been well known by the ordinary artisan for over a decade that hemopoietic stem and progenitor cells express CD34, and that various means for known and used to select such $CD34^+$ hemopoietic stem cells as taught by Tsukamoto et al. (see entire document, including Summary fo the Invention and Description of the Specific Embodiments.

In order to increase the efficiency and, in turn, the efficacy of hemopoietic stem cell populations, one of ordinary skill in the art at the time the invention was made would have been motivated to employ the methods of isolating CD34+ hemopoietic stem and progenitor cells as taught by Tsukamoto et al. prior to their exposure to FLT3 ligand GM-CSF in the methods taught by Lyman et al. for various therapeutic modalities associated with the useof hemopoietic stem cells, including transplantation of such cells known and practiced at the time the invention was made (see the Detailed Description in both Lyman et al. and Tsukamoto et al.). From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 30, 2004